UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,262	08/27/2003	Yerramilli V.S.N. Murthy	027585-000801US	6595

20350 7590 01/30/2009

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
01/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/650,262	MURTHY ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-14,44 and 59-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-14,44 and 59-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-14, 44 and 59-70 are pending in this application.

Applicants' arguments filed October 28, 2008 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-8, 11, 12, 14, 44, 59-64, 67, 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. U.S. Patent No. 6,309,663 B1.

Patel et al. teach a pharmaceutical composition for oral or parenteral use (column 41, lines 44-54) comprising active agents such as gentamycin (antibiotic) and fluoxetine (column 30, lines 33 and 36) combined with hydrophobic surfactants (water immiscible solvent) such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). It differs in that it does not specifically identify the components and "lipophilic counter ions", "water immiscible solvents" or "clear solutions". However,

"Products of identical chemical composition (i.e. decanoic acid/lipophilic counter ion) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. the release of the active compound over time) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). It would have been made obvious to one of ordinary skill in art at the time it was made to combine an active agent such as gentamycin and fluoxetine (see column 30, lines 3 and 36) with a water immiscible solvent such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). motivated by the teaching of Patel et al. that the composition is a successful carrier for oral and injectable agents.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be

commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-14, 44 and 59-70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 10-12, 17-19, 27-30 and 38-41 of U.S. Patent No. 7,033,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because The instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 1 requires di-lauric acid salt of tilmicosin and a pharmaceutically acceptable solvent wherein at least a portion of the di-lauric acid salt of tilmicosin is dissolved in the solvent. None of the instant claims recites that specific combination, but instant claims 1, 3-14, 44 and 59-70 are broadly inclusive thereof. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Claims 1, 3-14, 44 and 59-70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-10 and 14-19 of U.S. Patent No. 7,404,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting

claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 1 requires a composition comprising a salt comprising a pharmaceutically active compound and a lipophilic counter ion and a pharmaceutically acceptable solvent wherein the salt and the solvent form a solution. Instant claims 1, 3-14, 44 and 59-70 are broadly inclusive thereof because they are inclusive of a pharmaceutically active compound and a lipophilic counter ion and a pharmaceutically acceptable immiscible solvent. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Claims 1, 3-14, 44 and 59-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 13-20 and 32-35 of copending Application No. 10/974833. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 1 requires a composition comprising a sustained release composition comprising a proton donating pharmacologically active ingredient and a proton accepting pharmacologically active ingredient and a non-aqueous solvent in an injectable form that releases over

time. Instant claims 1, 3-14, 44 and 59-70 are broadly inclusive thereof because they are inclusive of a composition wherein a salt is formed of a pharmaceutically active compound (proton donator) and a lipophilic counter ion (proton acceptor) and a pharmaceutically acceptable immiscible solvent (non-aqueous) in an injectable form that releases the active compound over time. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-14, 44 and 59-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 65-138 of copending Application No. 11/088922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 65 requires an active agent, a lipophilic counter ion and a pharmaceutically acceptable solvent; however, the claims contain the same elements as recited in the instant claims, e.g., active agents such as tilmicosin, lipophilic counter ions such as decanoic acid and solvents such as linoleic acid. The instant claims require elements such as e.g. active

agents such as tilmicosin, a lipophilic counter ion such as decanoic acid and a water immiscible solvent such as linoleic acid (note linoleic acid is listed in the instant claims as a lipophilic counter ion and as a water immiscible solvent). None of the instant claims recites that specific combination, but instant claims 1-14 and 44-70 are broadly inclusive thereof. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical composition, the properties applicant discloses and/or claims (i.e. water immiscible solvent and lipophilic counterion) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant asserts that Patel does not disclose each and every feature of the invention recited in independent claims 1 and 44 because it does not disclose or suggest forming a salt comprising a pharmacologically active compound and a lipophilic

counterion or to combine the resulting salt with a water miscible solvent. In response, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Applicant further asserts that Patel does not disclose a composition that "when administered to an animal, forms a depot that releases the active compound over time". In response, Patel et al. teach that the administration of the invention of the patent increases the rate and/or extent of bioabsorption (column 3, lines 64-65). Although it does not specifically disclose a "cohesive oily mass" the elements of this claim are encompassed in the prior art as recited supra. Applicant asserts that gentamycin and fluoxetine are included in a list of pharmacologically active compounds that spans 3 columns of the patent. In response, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Exparte A*, 17. USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. *The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed*

was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that 'the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. 102(a), in that publication.'). Id. at 1718. See also *In re Simvaramakrishnan,* 673 F.2d 1383, 213 USPQ 441 (CCPA 1982)." In this case, the species "ionizable surfactants" are clearly named, although applicant has employed a different nomenclature (lipophilic counter ions). Regarding Applicant asserts that because Patel et al. teach a very small particle size, that the composition must not form a depot. In response, the particle size of the instant composition is not disclosed. Patel et al. teach a composition comprising active agents such as gentamycin (antibiotic) and fluoxetine (column 30, lines 33 and 36) combined with hydrophobic surfactants (water immiscible solvent) such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). It differs in that it does not specifically identify the components and "lipophilic counter ions", "water immiscible solvents" or "clear solutions". However, "Products of identical chemical composition (i.e. decanoic acid/lipophilic counter ion) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. the release of the active compound over time) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the amounts of each component of the composition, the ratio of components and how the components are combined and processed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant assets that the teaching that fluoxetine has an elimination half life of 1 to 3 days is not a teaching of a composition that "releases the active compound over time". The Examiner disagrees. Because of the half-life of fluoxetine being 1 to 3 days and in light of the same elements in the composition (hydrophobic surfactants and ionizable, ionized surfactants along with the claimed active agent), rate of delivery of the active compound is obvious.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

It is not clear to the Examiner what picking and choosing is needed in order to determine what medicaments are specifically described in Patel et al. to determine which agents are included as part of the invention. All that is needed to implement the disclosure of Patel et al. is to combine any of the agents recited (the patent is drawn to formulation of selected hydrophilic agents that have poor bioabsorption) with the water immiscible solvents recited along with a decanoic acid. There does not appear to be any difficulty in arriving at the decision of which agent to choose.

Applicant asserts that "the issue is not what is needed to implement the disclosure of Patel et al., the issue is what is needed to implement the claimed invention in view of Patel". Applicant again asserts that the vast disclosure of Patel et al. does not provide a motivation or suggestion to select the specific combination of components required to arrive at Applicant's invention. In response, when there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense". If there was a limited number of methods available, the skilled artisan would have had reason to try these methods, with the reasonable expectation that at least one would be successful.

Applicant asserts that the difference between Ex Parte A and the instant case is Applicants composition is not a species that has been selected from a list of species in Patel. In response, the Examiner is not in agreement. It appears that the compositions instantly claimed are selected from a list of a list of active compounds (gentamycin and

fluoxetine (column 30, lines 33 and 36)), the "lipophilic counterion" is the same as Patel et al's ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). The water immiscible solvent is disclosed in Patel et al. as hydrophobic surfactants with overlapping components such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12).

Applicant has requested that the double patenting rejections be held in abeyance until all rejections of the claims over prior art have been addressed.

Applicant asserts that the provisional double patenting rejection over the '833 application is improper because the '833 application was filed on October 28, 2004 and claims benefit of provisional 60/516,967 filed October 29, 2003 so that the instant case predates the provisionally rejected case. In response, disclaiming each one of the conflicting double patenting references is necessary to avoid the problem of dual ownership of patents to patentably indistinct inventions in the event that the patent issuing from the application being examined ceases to be commonly owned with any one of the double patenting references that have issued or may issue as a patent. Note that 37 CFR 1.31(c)(3) requires that a terminal disclaimer include a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the rejection. This requirement serves to avoid the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention (37 CFR 1.601(n)).

See, e.g., In re Van Ornum, 686 F.2d 937, 944-48, 214 USPQ 761, 767*70 (CCPA 1982).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

January 26, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614